

### DETAILED ACTION

#### Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 29-30, 32, 34-39, 42-47 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rava et al (US Pat: 6,697,665) stand alone or in view Helfer et al (US Pat: 5,197,470).

Regarding claims 29-30, 34, 42-43 and 50 Rava et al disclose a spectroscopic method to obtain molecular vibration information with attenuated total reflectance (ATR) of infrared light [see column 8 lines 31-34]. Rava et al disclose in figs 12A and 12B diagnostic measurements within the human body; probe 100 with one or more optical fibers 102 both the incident light to, and the transmitted (reflected) light from, the ATR element 104. A 100% infrared reflector 106 such as gold is placed at the distal surface 108 of the ATR element 104 functions to return the transmitted light back through the same fiber [see column 9 lines 11-25].

Rava et al further disclose irradiating a subsurface portion of atherosclerotic tissue within a vascular lumen to be diagnosed with radiation having a frequency within the infrared range transmitted through a fiber optic cable [see claim 1, Rava et al] and further mention the detecting step further comprises collecting the emitted light through the fiber optic cable [see claim 2] and determining chemical compositions and cellular conditions [see column 11 lines 1-25, column 13 lines 1-20, 42-45, column 16 lines 66-67 and column 17 lines 1-10].

Rava et al disclose IR beam from FT-IR is transmitted through IR optical fiber 122 to ATR element 128 positioned at the distal end of catheter body 120. The Transmitted light is conducted through second IR optical fiber 124 back to an IR detector [see column 9 lines 33-44]. Rava et al disclose radiation is transmitted 112 and collected 114 from element 104 [see column 9 lines 20-32, figs 12A-B].

Rava et al disclose computer 215 that stores information in a memory as a spectrum which is a graph of intensity vs wavelength which can be displayed on display 82 or compared with existing spectrum stored in the computer; and further mention the comparative data is shown in a display to provide quantitative measure of the health of the tissue observed [see column 4 lines 55-68].

Rava et al further disclose comparing mid-IR of a normal tissue to atherosclerotic plaque and observe increases in several bands in the atherosclerotic regions [see column 13 lines 46-60]. Rava et al disclose mid-infrared spectra were measured from 4000 to 700  $\text{cm}^{-1}$  with IR spectrometer [see column 8 lines 31-34 and column 12 lines 56-67].

Rava et al may not explicitly mention a tissue at a location inside a blood vessel.

However, Rava et al disclose the probe can either be inserted through a standard endoscope or catheter to sample a hollow organ (or artery) [see column 9 lines 20-32] which is a blood vessel.

Nonetheless, Helfer et al disclose optical means for transmitting and receiving light energy from the fibers to a blood vessel and from the illuminated blood vessel to the fibers, respectively; means for delivering the generated energy to the at least one

fiber, means for detecting the amount of such generated energy that is not absorbed by illuminated tissue in a blood vessel and means for discriminating illuminated healthy tissue from illuminated diseased tissue [see column 3 lines 45-65]. Helfer et al disclose atherosclerosis in all kinds of blood vessels is diagnosed using reflected wavelengths particularly effective in being absorbed by disease states of such vessels, such as plaque [see column 5 lines 7-15].

In the alternative, one skilled in the art at the time the invention was made would have been motivated to combine Rava et al with Helfer et al by diagnosing a tissue inside a blood vessel; in order to diagnose blood flow for hidden diseases.

Regarding claims 32, 35, Rava et al disclose mid-infrared spectra were measured from 4000 to 700  $\text{cm}^{-1}$  with IR spectrometer [see column 8 lines 31-34 and column 12 lines 56-67].

Regarding claim 36, Rava et al disclose computer 215 that stores information in a memory as a spectrum which is a graph of intensity vs wavelength [see column 4 lines 55-68]. Rava et al disclose mid-infrared spectra were measured from 4000 to 700  $\text{cm}^{-1}$  with IR spectrometer [see column 8 lines 31-34 and column 12 lines 56-67] which means the computer is operable to store any wavelength or wavenumber within the range of 4000 to 700  $\text{cm}^{-1}$ .

Regarding claim 37, Rava et al disclose an interferometer [see fig 1C].

Regarding claim 38, Rava et al disclose a source fiber and a detection fiber having a tip [see column 9 lines 11-45].

Regarding claim 39, Rava et al disclose an optical fiber selector 217 [see column 4 lines 35-68].

In addition, Helfer et al disclose Switching mechanism 32 is used to switch the laser to an appropriate fiber, which can be the same switching mechanism as described for illuminating each of the optic fibers 15 with light from source 22 [see column 6 lines 33-45] which is a tuning system.

Regarding claims 44-47, Rava et al further disclose irradiating a subsurface portion of atherosclerotic tissue within a vascular lumen to be diagnosed with radiation having a frequency within the infrared range transmitted through a fiber optic cable [see claim 1, Rava et al] and further mention the detecting step further comprises collecting the emitted light through the fiber optic cable [see claim 2].

Rava et al disclose the method of spectroscopic diagnosis wherein the coupling step further comprises providing a catheter for insertion into body lumens and the fiber optic cable receives light emitted by the tissue and transmits the emitted light to a spectroscopic analysis system [see claims 4-5].

3. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rava et al (US Pat: 6,697,665) in view Helfer et al (US Pat: 5,197,470) as applied to claim 34 above and further in view of Alfano et al (US Pat: 5,293,872).

Rava et al don't teach a cooling means for the detector.

Nonetheless, Alfano et al teach a liquid nitrogen cooled indium gallium arsenide photodiode type detector [see column 5 lines 21-23].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Rava et al with Alfano by using a liquid cooled type detector; in order to minimize overheating of the detector.

4. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rava et al (US Pat: 6,697,665) in view Helfer et al (US Pat: 5,197,470) as applied to claim 34 above and further in view of Corenman et al (US Pat: 4,817,013).

Regarding claim 41, all other limitations are taught as set forth by the above combination.

Rava et al don't teach customized bandwidth and special gain for DC or AC preamps.

Nonetheless, Corenman et al teaches preamp [see 6C]; fig 4A shows AC/DC separation circuit in the amplifiers that receive signal output from three infrared detectors.

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Rava et al with Corenman et al r; for the purpose of providing a more efficient system by improving its performance.

5. Claims 33 and 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rava et al (US Pat: 6,697,665) in view Helfer et al (US Pat: 5,197,470) as applied to claim 34 above and further in view of Dumoulin et al (US Pat: 6,129,667).

Regarding claims 33 and 48-49, Rava et al don't explicitly mention whether the optical cable 145 is rotatable within the body lumen.

However, it is well known in the art that catheters and endoscope are rotatable within a body lumen such as a blood vessel (emphasis added). Therefore, it is inherent that the fiber optic cable rotates radially within the blood vessel to acquire data at various locations; thus performing 360 degrees spectral analysis (emphasis added).

Nonetheless, Dumoulin et al disclose a fiber optic cable running through an invasive device and the fiber optic cable is rotatable [see claim 3] to acquire data at various locations. Dumoulin et al further disclose creating a tissue map of lumen [see claim 3] which is capable of generating a map of reflectance spectral signals from different locations within the blood vessel.

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Rava et al with Dumoulin et al by using the fiber optic cable that rotates within the catheter; in order to have full coverage of the area and to provide an accurate diagnosis of the tissue of interest with the spectral map.

#### **Response to Arguments**

6. Applicant's arguments filed February 18, 2011 have been considered but are moot in view of the new ground(s) of rejection.

**Conclusion**

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/J. F. B./  
Examiner, Art Unit 3777

/Tse Chen/

Supervisory Patent Examiner, Art Unit 3777